



AliMed® inc.

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K 963527

**510(k) SUMMARY
Various General Purpose Straps**

Applicant:

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Trade Name: Universal Econo-Strap, QualCraft™ Universal Straps
Common Name: Strap
Classification Name: Patient Restraint

Legally Marketed Devices to Which Substantial Equivalence is claimed:

Various Preamendments General Purpose Straps

510(k) SUMMARY-continued

Description of Device: The devices are fabricated using nylon or nylon and polyethol foam of various lengths and widths as described in advertising. The closure is Velcro® or Velcro®-like hook and loop.

Intended Use of the Device: Reduce patient movement in recover, in bed, or other uses as determined by the health care professional user.

CODE	NAME	SIZE	FIRST MANUFACTURED	USE
7536	Econo-strap	3" x 72"	1990	General purpose strap
7539	Econo-strap	4" x 75"	1990	General purpose strap
91-277	Universal 1 piece	2" x 76"	1989	General purpose strap
91-278	Universal 1 piece	3" x 76"	1989	General purpose strap
91-279	Universal 1 piece	4" x 76"	1989	General purpose strap
91-280	Universal 1 piece	6" x 76"	1989	General purpose strap
91-281	Universal 1 piece	2" x 96"	1989	General purpose strap
91-282	Universal 1 piece	3" x 96"	1989	General purpose strap
91-283	Universal 1 piece	4" x 96"	1989	General purpose strap
91-284	Universal 1 piece	6" x 96"	1989	General purpose strap
91-285	Universal 2 piece	2"	1989	General purpose straps
91-286	Universal 2 piece	3"	1989	General purpose straps
91-287	Universal 2 piece	4"	1989	General purpose straps
91-288	Universal 2 piece	6"	1989	General purpose straps
91-596	Universal 1 piece	2" x 65"	1994	General purpose strap
91-597	Universal 1 piece	3" x 65"	1994	General purpose strap
91-598	Universal 1 piece	4" x 65"	1994	General purpose strap
91-599	Universal 1 piece	6" x 65"	1994	General purpose strap

510(k) SUMMARY-continued

Comparative Information: The firm has been unable to locate pre-Amendment catalogs, or similar materials, which relate to this type of general purpose strap. However, it is generally known that they were in use prior to May of 1976 and that they have continued to be supplied by other firms since that time.

Biocompatibility: Based on the materials used in construction of these straps, and the topological application with the normal use arrangement having some other material between the patient's skin and the strap, there is little likelihood of a biocompatibility concern arising.

User Experience: The firm has received no information related to a death, serious injury or allergic reaction to the materials during the time these devices have been manufactured.